4. PROGRAM REQUIREMENTS

428.401: Introduction

130 CMR 428.000 states the requirements and procedures for the purchase and repair of prosthetic devices, customized equipment, and supplies under MassHealth. All providers of prosthetic services participating in MassHealth must comply with the regulations of the Division governing MassHealth, including, but not limited to, Division regulations set forth in 130 CMR 428.000 and in 130 CMR 450.000.

428.402: Definitions

The following terms used in 130 CMR 428.000 have the meanings given in 130 CMR 428.402 unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 428.000 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 428.000 and in 130 CMR 450.000.

Accessory Equipment — equipment that is fabricated primarily and customarily to modify or enhance the usefulness or functional capability of another piece of prosthetic equipment and that is generally not useful in the absence of such prosthetic equipment.

Adjusted Acquisition Cost — except where the manufacturer is the provider, the price paid by the provider to the manufacturer or any other supplier for prosthetic devices, customized equipment, or supplies, excluding all associated costs such as shipping, handling, and insurance costs in accordance with 130 CMR 428.422. Where the manufacturer is the provider, the adjusted acquisition cost is the actual cost of manufacturing such prosthetic devices, customized equipment, or supplies.

Date of Service — the date the prosthesis is delivered and fitted to the MassHealth member. If the prosthetic service involves a series of fittings and adjustments, the date of service is the date on which the final adjustment is made. If the prosthetic service involves only the provision of a service (for example, a repair), then the date of service is the date on which the service was completed.

Discount — any remuneration or reduction of payment of any kind, whether direct or indirect, received by the provider.

Nursing Facility — a licensed facility that meets the provider-eligibility and certification requirements of 130 CMR 456.404 or 456.405 and whose members meet the medical eligibility criteria under 130 CMR 456.409. Nursing facilities do not include facilities such as rest homes, state schools, and state hospitals.

Nursing Facility Visit — a visit by a provider to a nursing facility for the purpose of providing prosthetic services.

Prosthesis (or Prosthetic Equipment) — an artificial replacement for a missing body part, such as an artificial limb or total joint replacement.

Prosthetic Service — the purchase, customization, fitting, repair, replacement, or adjustment of a prosthesis or component part, or other activity performed or equipment provided in accordance with 130 CMR 428.000.

Prosthetic Supplies — products that are:

(1) fabricated primarily and customarily to fulfill a medical purpose;
(2) used in conjunction with a prosthesis or prosthetic equipment;
(3) generally not useful in the absence of a prosthesis; and
(4) non-reusable and disposable.

Prosthetics — the design, fitting, and attachment of an artificial replacement of a missing body part.

Service Facility — the place of business, physically accessible to MassHealth members, where prosthetic services, especially those involving fitting, adjustment, repair, and replacement of prostheses, are performed. A service facility does not include a MassHealth member's place of residence.

428.403: Eligible Members

(A) (1) MassHealth Members. The Division covers prosthetic services only when provided to eligible MassHealth members, subject to the restrictions and limitations in130 CMR 428.000 and 450.000. 130 CMR 450.105 specifically states, for each coverage type, which services are covered and which members are eligible to receive those services.
(2) Age Limitations. In addition to any other restrictions and limitations set forth in 130 CMR 428.000 and 450.000, the Division covers prosthetic services only when provided to eligible MassHealth members, subject to the age limitations set forth in Subchapter 6 of the *Prosthetics Manual*.
(3) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.

(B) For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

428.404: Provider Eligibility

For services described in 130 CMR 428.000, the Division pays only those providers of prosthetic services who are participating in MassHealth as of the date of service.

(A) In State. To participate in MassHealth, a provider with a service facility in Massachusetts must:

(1) primarily engage in the business of providing prosthetic and repair services to the public;
(2) meet all state and local requirements for engaging in such business;
(3) be or employ a prosthetist currently certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or the Board for Orthotics/Prosthetics Certification.
(4) be a Medicare provider;
(5) have a service facility that is physically accessible to MassHealth members during reasonable business hours;
(6) maintain a visible sign identifying the business and hours of operation; and
(7) maintain a primary business telephone listed under the name of the business in a local directory. The exclusive use of a pager, answering machine, or cell phone is prohibited.

(B) Out of State. A provider with no service facility in Massachusetts may participate in MassHealth only if the provider participates in the medical assistance program of the state in which the provider primarily conducts business and otherwise meets the requirements of 130 CMR 428.404(A). Such a provider may receive payment for MassHealth services only as set forth in 130 CMR 450.109.

428.405: Provider Responsibility

(A) The provider must ensure that all prosthetic equipment and supplies are:

(1) clean (sterilized when appropriate);
(2) in proper working condition;
(3) functional;
(4) free from defects; and
(5) new and unused at the time of purchase.

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(B) The provider must ensure that all prosthetic services are the most cost effective, given the medical need for which they are prescribed and the member's physical limitations.

(C) The provider must make a reasonable effort to purchase the item from the least costly reliable source by comparing prices charged by different suppliers for comparable items.

428.406: Covered Services

The Division pays for only those prosthetic services listed in, and subject to the service limitations set forth in, Subchapter 6 of the *Prosthetics Manual*.

428.407: Service Limitations

The service limitations set forth in Subchapter 6 of the *Prosthetics Manual* apply, subject to the Early and Periodic Screening, Diagnosis, and Treatment provisions set forth in 130 CMR 450.144(A).

428.408: Noncovered Services

The Division does not pay for any of the following:

(A) any prosthetic services for which, under comparable circumstances, the provider does not customarily bill private patients who do not have health insurance;

(B) nonmedical prosthetic services. Equipment that is used primarily and customarily for a nonmedical purpose is not considered medical equipment, even if such equipment has a medically related use;

(C) storage of prosthetic equipment or associated items; and

(D) prosthetic services that are not both medically necessary in accordance with 130 CMR 450.204 and reasonable for the treatment of a member's condition. This includes services that:

(1) cannot reasonably be expected to make a meaningful contribution to the treatment of a member's condition or the performance of the member's activities of daily living; and
(2) are more costly than a medically comparable and suitable alternative or that serve essentially the same purpose as equipment already available to the member.

428.409: Prescription Requirements

(A) The purchase of prosthetic equipment requires a written prescription signed by a licensed physician or an independent nurse practitioner. The prescription must be written on the prescriber's prescription form and must include the following information:

(1) the member's name and address;
(2) the member's MassHealth identification number;
(3) specific identification of the prescribed item;
(4) medical justification for the use of the item, including the member's diagnosis;
(5) the prescriber's address and telephone number; and
(6) the date on which the prescription was signed by the prescriber.

(B) The provider must keep the prescription on file for the period of time required by 130 CMR 450.205.

428.410: Prosthetic Equipment Provided to Institutionalized Members

(A) Nursing Facilities. The Division pays prosthetic providers for:
(1) the purchase and repair of prosthetic equipment; and
(2) prosthetic supplies provided for the personal full-time use of a member residing in a nursing facility.

(B) Institutions Licensed as Hospitals, Chronic Disease Hospitals, and Rehabilitation Hospitals. The Division does not pay prosthetic providers for the purchase or repair of prosthetic equipment or for supplies provided to a hospitalized member, except for prosthetic equipment that is prescribed for home use after discharge. The hospital record must document the member's discharge plan and that the date of discharge was before the purchase or repair of the prescribed item.

(C) Intermediate Care Facilities for the Mentally Retarded with 16 Beds or More (State Schools).
(1) The Division pays prosthetic providers or the purchase and repair of customized prosthetic equipment provided for the personal full-time use of a member residing in an ICF/MR with 16 beds or more (a state school) only if the customization precludes the use of the equipment by subsequent residents in that institution.
(2) The Division does not pay prosthetic providers for noncustomized equipment or supplies provided to a member residing in a state school.

(D) Rest Homes. The Division pays prosthetic providers for the purchase and repair of prosthetic equipment and for associated supplies provided for the personal full-time use of a member residing in a rest home.

428.411: Repairs of Prosthetic Equipment

(A) The Division pays for all repair services on an individual-consideration basis as described in 130 CMR 428.422.

(B) The provider of repair services is liable for the quality of the workmanship and parts, and for ensuring that repaired equipment is in proper working condition.

(C) The provider of repair services must exhaust all manufacturer warrantees before submitting claims for repairs to prosthetic equipment to the Division.

428.412: Prior Authorization

(A) Services that require prior authorization as a prerequisite for payment are identified in the Division's regulations at 130 CMR 428.000 or are listed in Subchapter 6 of the *Prosthetics Manual* with the designation "(P.A.)" appearing after the service description. To determine if prior authorization is required, the provider should review both the regulations and Subchapter 6. Prior authorization determines only the medical necessity of the prescribed item or service and does not waive any other prerequisites to payment such as member eligibility or resort to health-insurance payment.

(B) The provider must request prior authorization in accordance with the billing instructions in Subchapter 5 of the *Prosthetics Manual*. Before determining the medical necessity of an item or service for which prior authorization is requested, the Division may, at its discretion, require the prescriber to submit an assessment of the member's condition and the objectives of the requested service. The Division may also, at its discretion, require an evaluation by a licensed prosthetist to determine whether the requested prosthetic service is useful to the member, given the member's physical condition and physical environment.

(C) (1) The Division will send notification to the member and the provider of the following prior-authorization decisions:

(a) approval;
(b) modification; or
(c) denial.

(2) If the Division defers the prior-authorization decision because additional information is required to determine whether the requested service is medically necessary, the Division will notify the provider.

(3) If the Division denies or modifies a request, the notification will include the reason for the Division's determination. The member may appeal the modification or denial of a prior-authorization request within 30 days after the date of the notice. Procedures for such an appeal are set forth in 130 CMR 610.000.

(D) The Division will make a decision on the request within 15 days after the date of receipt of a fully completed prior-authorization request. The Division will confirm the date of receipt and the date of action upon written request.

(E) The provider must keep the prior-authorization request on file for the period of time required by 130 CMR 450.205.

428.413: Procedure for Requesting Prior Authorization

(A) The provider must obtain prior authorization from the Division before providing any service that requires prior authorization. The provider must submit the Request for Prior Authorization within 90 days of the date of service requested on the prescription.

(B) The Request for Prior Authorization must document the adjusted acquisition cost (see 130 CMR 428.421) and the medical necessity of the requested service. The Request for Prior Authorization must contain the following documentation:

(1) a copy of the invoice or invoices from the manufacturer for the equipment, disclosing all discounts;
(2) a copy of a current prescription that must not be older than 90 days from the requested date of service (see 130 CMR 428.409 for information that must be included in the prescription);
(3) if requested by the Division, a current prosthetic evaluation for the equipment, performed independently of the provider by a licensed physician or prosthetist;
(4) the date or projected date of service;
(5) the projected duration of need for the equipment; and
(6) if replacing existing equipment, the date the existing equipment was purchased.

428.414: Medicare Coverage

(A) For Medicare and third-party-liability coverage, see 130 CMR 450.316 through 450.318.

(B) For Medicare-covered services that are provided to members who receive Medicare Part B benefits, the Division does not require prior authorization.

(C) When Medicare denies a claim for prosthetic services or considers the services uncovered, the Division requires prior authorization for those services that would require prior authorization for members without Medicare.

(130 CMR 428.415 through 428.419 Reserved)

428.420: Payment for Prosthetic Services

(A) Payment to a provider for prosthetic equipment and supplies is subject to the conditions and limitations in 130 CMR 428.000 and 450.000, and will be the lower of:

(1) the provider's usual and customary charge to the general public; or

(2) the fee set forth in the schedule of maximum allowable fees established by the Massachusetts Division of Health Care Finance and Policy.

(B) Payment for the following services is included in the provider payment under 130 CMR 428.420(A). No separate payment is allowed for:

(1) the fitting of the prosthesis;

(2) instructing the member in the use of the prosthesis;

(3) the cost of the component parts and accessory equipment;

(4) repairs due to normal wear and tear within 90 days of the date of delivery; and

(5) adjustments to the prosthesis and any prosthetic component made when fitting the prosthesis and for 90 days from the date of delivery, when the adjustments are not necessitated by changes in the member's functional abilities.

428.421: Individual Consideration

When the rate of payment for the purchase or repair of certain prosthetic equipment has not been established by the Division of Health Care Finance and Policy, the Division pays for the service based on individual consideration, subject to all other conditions of payment. Such items are identified in Subchapter 6 of the *Prosthetics Manual* by the designation "(I.C.)" next to the description of the item or service. The Division determines the rate of payment for an individual-consideration item or service based on the provider's report of services and a current invoice that indicates the provider's adjusted acquisition cost as defined in 130 CMR 428.421 and 428.422. Payment for the fitting of a prosthesis is included in the adjusted acquisition cost. Providers must maintain adequate records to document the individual consideration claim and must provide these documents to the Division and the Attorney General's Medicaid Fraud Control Unit upon demand (see 130 CMR 450.205). Payment to a provider for an individual consideration claim is the lower of:

(A) the provider's usual and customary charge to the general public; or

(B) the adjusted acquisition cost of the item plus a markup not to exceed:

(1) 70 percent for any item whose adjusted acquisition cost is less than $100;

(2) 50 percent for any item whose adjusted acquisition cost is $100 or greater and less than $200;

(3) 45 percent for any item whose adjusted acquisition cost is $200 or greater and less than $300; or

(4) 40 percent for any item whose adjusted acquisition cost is $300 or greater.

428.422: Adjusted Acquisition Cost

(A) The provider must disclose all discounts, as defined in 130 CMR 428.402, and must reflect such discounts in the provider's claim for payment pursuant to M.G.L. c. 118E, § 41, and U.S.C. § 1320a-7b(b)(3)(A). Any provider who fails to disclose and pass on any discounts to the Division may be subject to civil and criminal penalties, including imprisonment, in accordance with state and federal laws.

(B) (1) Except where the manufacturer is the provider, the adjusted acquisition cost must not exceed the manufacturer's current wholesale price and must be evidenced by the purchase price of the equipment or goods listed on a copy of the supplier's invoice.
(2) Where the manufacturer is the provider, the adjusted acquisition cost must not exceed the actual cost of manufacturing the items.

(C) Where the manufacturer is the provider of any item covered under 130 CMR 428.000, the manufacturer must submit documentation that demonstrates to the Division's satisfaction the actual cost of manufacturing the item, as set forth in 130 CMR 428.421(B).

(D) The provider must maintain the actual receipted invoice in the member's record, and make it available to the Division and the Attorney General's Medicaid Fraud Control Unit pursuant to 130 CMR 428.434 and 450.205.

(E) The provider may group together low-cost items (those with an adjusted acquisition cost of less than $5 each) to equal $5 or less, and bill the total adjusted acquisition cost plus the allowable markup listed in 130 CMR 428.422(B).

428.423: Recordkeeping Requirements

The provider must keep a record of all prosthetic services, nursing facility visits, and the medical necessity of such services provided to a member for the period of time required by 130 CMR 450.205. This record must include the following:

(A) a prescription for all purchases;

(B) a copy of the approved prior-authorization request for all prosthetic services requiring prior authorization;

(C) an acknowledgment of receipt, signed by the member or the member's representative, of prescribed equipment or supplies, including:
(1) the date of receipt of equipment or supplies;
(2) the condition of the equipment or supplies (for example, whether it is in proper working order or is damaged);
(3) the manufacturer, brand name, model number, and serial number of the equipment or supplies;

(4) for repair services, a complete description of the service, including the manufacturer, brand name, model number, and serial number of the repaired item; and

(5) next to the signature, an explanation of the representative's relationship to the member by the individual acknowledging receipt. This individual cannot be associated with either the provider or the delivery service.

(a) For routine delivery of supplies, the member must acknowledge receipt at least monthly.

(b) A signature stamp may be used by or on behalf of a MassHealth member whose disability inhibits the member's ability to write. A signature stamp may only be used by a member or the member's representative, provided that the stamp is used by the member in his or her normal course of conducting business. A signature stamp cannot be used by anyone associated with either the provider or the delivery service;

(D) the actual invoice showing the cost to the provider of the materials (if the provider is not the manufacturer of the materials);

(E) documentation demonstrating the cost of manufacturing the item provided (if the provider is the manufacturer);

(F) copies of written warranties; and

(G) documentation demonstrating efforts under 130 CMR 428.405(C) to purchase the item from the least costly reliable source.

REGULATORY AUTHORITY

130 CMR 428.000: M.G.L. c. 118E, §§ 7 and 12.